REMARKS

Claims 1-116 are pending.

The amendments to the claims are supported by the original disclosure and, thus, no new matter has been added. But if the Examiner should disagree, she is respectfully requested to point out the challenged limitation with particularity in the next Office Action so support may be cited in response.

In view of the new requirement made in Paper No. 9, Applicants will instead elect Group II (original claims 45-46, 69 and 73-74), drawn to a method for transcutaneous immunization using a nucleic acid, for examination on the merits.

Support for the new and amended claims can be found in original claims 45-46, 69 and 73-74; page 14, lines 1-12, and page 36, line 16, to page 37, line 12, of the specification; Examples 19, 34 and 38. Use of nucleic acid was described in Applicants' U.S. Patent No. 5,980,898 (filed July 17, 1997) on col. 14, lines 13-29.

The skin which is used can be intact, or exposed to the epidermal layer using a chemical or mechanical penetration enhancer. See page 7, lines 2-13 and 20-23; page 8, lines 7-12; and page 124, lines 15-17, of the specification. With the mouse model used in the examples, the fur/hair is generally shaved prior to transcutaneous immunization. But hair-containing skin can also be used as described on page 18, line 8-9, and page 79, line 3, of the specification. For example, where fur/hair would not prevent application of the immunization solution (cf. the ear of a mouse or the arm of a human volunteer to the *shaved* dorsum on page 40, lines 4-5, of the specification), removal of the fur/hair from the skin prior to transcutaneous immunization would not be necessary.

With respect to the requirement to elect a species for examination, Applicants elect parasite antigens as a specific antigen, Plasmodium as a specific subspecies of parasites, pathogen-associated molecular patterns (PAMPs) as a specific adjuvant, and unmethylated CpG motifs as a specific subspecies of PAMPs. Claims 1-31, 35-36, 43-46 and 55-116 read on the elected antigens. Claims 1-58, 68-70 and 72-116 read on the elected adjuvants.

The new claims 102-116 are added to provoke an interference under 37 CFR § 1.607 between this application and U.S. Patent No. 6,087,341 (copy attached)

issued July 11, 2000. The latter has an effective filing date of February 12, 1998, which is subsequent to Applicants' effective filing date.

New claims 102-116 represent copies of claims 1-15 of the patent. The differences in claim language are inconsequential modifications (e.g., organism instead of vertebrate, penetration enhancer instead of irritant) so as to accommodate for differences between the disclosures of Applicants and the patent.

It is believed that an appropriate interference count would be patent claim 1 and/or Applicants' claim 102. If so, patent claims 1-16 and Applicants' claims 102-116 would be directed to the same invention.

A substitute Form PTO-1449 is attached. Please use the attached in lieu of the previously submitted Form PTO-1449 that have been made of record. It is urged that use of the attached Form PTO-1449 will reduce possible confusion by the printer when this information is listed on the front of a patent because it represents an updated and consistent format for the references considered by the Examiner. Any references not submitted in this application were submitted to or cited by the Examiner in US 5,910,306; US 5,980,898; or related U.S. Appln. Nos. 08/749,164; 08/896,085; 09/157,395; 09/257,188; 09/266,803; 09/309,881; 09/316,069; 09/337,746; 09/545,417; and 09/585,559. The Examiner may wish to consider these related patent file wrappers and applications in prosecution of this application.

Applicants urge that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is needed.

Respectfully submitted,

Intellectual Property Group of
PILLSBURY WINTHROP, L.L.P.

By _____
Gary R. Tanigawa
Reg. No. 43180

1600 Tysons Boulevard
McLean, VA 22102
Telephone: (703) 905-2000

APPENDIX

MARKED-UP VERSION TO SHOW CHANGES

IN THE SPECIFICATION:

The specification is amended as follows.

Page 1, lines 4-11:

This application is a continuation in-part of U.S. Appln. No. 08/749,164 (filed November 14, 1996; now U.S. Patent No. 5,910,306 [and pending]); U.S. Appln. No. 08/896,085 (filed July 17, 1997; now U.S. Patent No. 5,980,898 [and pending]); PCT/US97/21324 designating the U.S. (filed November 14, 1997; now abandoned [and pending]); U.S. Appln. No. 09/257,188 (filed February 25, 1999 and pending); and U.S. Appln. No. 09/309,881 ["number not yet designated" (docket PMS254806,] (filed May 11, 1999 and pending). This application also claims priority benefit from provisional U.S. Appln. No. 60/086,196 (filed May 21, 1998). All patent applications cited herein, as well as patents issued therefrom, are incorporated by reference in their entirety.

Page 6, lines 27-30:

Furthermore, U.S. Appln. Nos. 09/257,188 and 09/309,881 ["number not yet designated" (docket PMS254806)] disclose penetration enhancers (e.g., removal of superficial layers above the dermis, micropenetration to above the dermis) and targeting of complexed antigen and/or adjuvant in the context of transcutaneous immunization.

IN THE CLAIMS:

The claims are amended as follows.

1. (Amended) A method for transcutaneous immunization comprising:

(a) providing a formulation comprised of at least one antigen and at least one adjuvant, wherein said at least one antigen or said at least one antigen is

provided as at least one polynucleotide encoding said at least one antigen or said at least one adjuvant;

(b) applying said formulation epicutaneously to skin of an organism without penetrating past dermis of said skin;[,] and

(c) inducing an antigen-specific immune response in said organism.

80. (Amended) A method for transcutaneous immunization of an organism comprising:

(a) providing a formulation comprised of at least one antigen and at least one adjuvant, wherein said at least one antigen or said at least one antigen is provided as at least one polynucleotide encoding said at least one antigen or said at least one adjuvant and enhancement of immunologic activity by said adjuvant is separable from an immunogenic epitope of said antigen;

(b) applying said formulation to skin of said organism; and

(c) inducing an immune response in said organism specific for said immunogenic epitope which is enhanced as compared to a formulation that does not contain said adjuvant activity.

93. (Amended) A formulation which comprises:

(a) at least one antigen, and

(b) at least one adjuvant;

wherein said at least one antigen or said at least one antigen is provided as at least one polynucleotide encoding said at least one antigen or said at least one adjuvant, enhancement of immunologic activity by said adjuvant is separable from an immunogenic epitope of said antigen, and said formulation induces an immune response specific for said immunogenic epitope which is enhanced as compared to a formulation that does not contain said adjuvant activity.

New claims 102-116 are added.